for identification and cloning of a nucleic acid, vector comprising the nucleic acid, host cell comprising the vector and a method of producing a polypeptide using the host cell, classified in Class 435, subclasses 69.1, 321.1, 325 and 455 and Class 536, subclass 23.5;

II. Claims 18, 36, 39 and 41, drawn to a hybridizing nucleic acid, a method of detecting expression of a tumor suppressor or for diagnosing a predisposition to a tumor or a disorder by using the hybridizing nucleic acid and the use of the nucleic acid to treat a disease classified in Class 435, subclass 6 and Class 536, subclass 23.5;

III. Claim 25, drawn to a polypeptide, classified in Class 530, subclass 350;

IV. Claims 26 and 37-38, drawn to an antibody and a method for detecting expression using the antibody, classified in Class 435, subclass 7.1 and Class 530, subclass 387.9;

V. Claims 27-35, 40, and 42-46, drawn to a pharmaceutical composition comprising a nucleic acid molecule, a complementary nucleic acid molecule or a vector, a polypeptide, an antibody; a diagnostic composition and methods and uses for treating a disease using the composition, classified in Class 424, subclass 139.1, Class 514, subclasses 12 and 44;

VI. Claims 47-48, drawn to a process for identifying

antagonists, inhibitors, agonists or activators to a tumor suppressor comprising use of the polypeptide of claim 25, classified in Class 435, subclass 29.

The Examiner stated that "Group V contains claims directed to the following patentably distinct species of the claimed invention: a nucleic acid molecule, a complementary nucleic acid molecule or a vector, a polypeptide, an antibody; if this group is elected, applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently none of the claims is generic."

The Examiner stated that the inventions are distinct, each from the other because of the following reasons: "Groups I-IV are different and distinct chemical compounds that are patentably distinct. Group V is drawn to all of the compounds of Groups I-IV as pharmaceutical and diagnostic compositions, and the use of them to treat diseases."

The Examiner also stated: "Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as to suppress tumors."

The Examiner stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper. The Examiner advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

In response to this restriction requirement, applicants hereby elect, with traverse, to prosecute the invention of Examiner's Group II, claims 18, 36, 39, and 41, drawn to a hybridizing nucleic acid, a method of detecting expression of a tumor suppressor or for diagnosing a predisposition to a tumor or a disorder by using the hybridizing nucleic acid and the use of the nucleic acid to treat a disease classified in class 435, subclass 6 and class 536, subclass 23.5.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction of Examiner's Group II from Examiner's Groups I and III-VI be withdrawn in view of the fact that the claims of Examiner's Group II are not independent of Examiner's Groups I and III-VI.

The inventions of Groups I-VI are not independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subjects disclosed. The inventions of Groups I-VI are related in that they relate to novel nucleic acid molecules coding for a protein having the biological activity of a tumor suppressor protein. Applicants, therefore, maintain that the claims of Groups I-VI are not independent. Applicants therefore maintain that restriction is improper.

Applicants, therefore, respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Moreover, applicants maintain that the claims of Groups II and I are not independent, since the claims of Group I are directed to nucleic acid molecules encoding a protein having the biological activity of a tumor suppressor selected from the group consisting of (a) - (c), wherein (a) are **nucleic acid molecules coding for a polypeptide** comprising amino acid sequence **given in SEQ ID NO:2**; (b) are **nucleic acid molecules comprising** the **nucleotide sequence given in SEQ ID NO:1**; (c) are nucleic acid molecules **hybridizing to a nucleic acid molecule as defined in (a) or (b)**; and (d) are **nucleic acid molecules, the nucleotide sequence of which is degenerate** a result of the genetic code **to a nucleotide sequence** of a nucleic acid molecule **as defined in (a), (b) or (c)** and the claims of Group II are directed to a nucleic acid molecule of at least 15 nucleotides in length

hybridizing specifically with a nucleic acid molecule **of claim 1** or with a nucleic acid molecule of any of claims 11 to 17 or to a complementary strand thereof. Accordingly, both Groups I and II recite claims which hybridize to the nucleic acid molecules of claim 1. Applicants maintain that the claims of Group I and II are linked to define a single general inventive concept: nucleic acid molecules as set forth in claim 1 and nucleic acid molecules hybridizing thereto, methods of identification and cloning thereof and methods of producing the encoded polypeptide (Group I), and, claims directed to a nucleic acid molecule of at least 15 nucleotides in length hybridizing specifically with a nucleic acid molecule of claim 1 or claims dependent thereon, which is a "nucleic acid molecule hybridizing to a nucleic acid molecule as defined in (a) or (b)" of claim 1, differing only on length of said nucleic acid molecule. Applicants also respectfully note that the classification of Groups II and I overlaps and both are classified in Class 536, subclass 23.5.

Accordingly, applicants maintain that restriction of Group I and II, at a minimum, should be withdrawn, since two or more independent and distinct inventions have not been claimed **and** there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art for Group II would necessarily identify art for Group I. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw, at least, the restriction requirement of Groups II and I and examine claims 1-24, 36, 39 and 41, on the merits.

Additionally, applicants point out that M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants further maintain that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art for Group II would necessarily identify art for Groups I and III-VI. Applicants therefore maintain that the search and examination of the claims of Group II in addition to the claims of Groups I and III-VI would not be a serious burden on the Examiner. Since there is no burden on the Examiner to examine the claims of Groups II, I, and III-VI of the subject application, applicants submit that the Examiner must examine the entire application on the merits, i.e. the inventions of Groups II, I and III-VI.

Applicants maintain that claims 1-48 define a single inventive concept. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-48 on the merits.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number

provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail addressed to:
Assistant Commissioner for Patents
Washington, D.C. 20231.

11/30/00
Date

John P. White
Reg. No. 28,678

John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400